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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/812,945 | 03/27/2001 | Hsuan-Yin Lan-Hargest | 12938-002001 | 5280 |
| 27890 | 7590 | 03/11/2005 | EXAMINER | |
| STEPTOE & JOHNSON LLP 1330 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036 | | | WANG, SHENGJUN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |
| DATE MAILED: 03/11/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,945

Applicant(s)

LAN-HARGEST ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-18, 21-24 and 32-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-7, 9-18, 21-24 and 32-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Reipt of applicants' amendments and remarks submitted November 3, 2004 is acknowledged. As indicated in the prior office action, the previous elected species are allowable in view of the decision of Board of patent Appeals and interferences. In view the complexity of the remain subject matters within the elected invention, following further restriction requirements are necessary.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, 4-7, 10, 12, 17, 18, 40-42, 44-46 drawn to a method of treating cancer by administering to the patient a compound of formula I, wherein the Y2 is a bond, L is an unsaturated C4 with two double bond optionally substituted with C1-2 alkyl, C6 with three double bonds or C8 with three double bond, X1, X2 together with the carbon attached is a hydroximic acid group, Y1 is CH2, classified in class 514, subclass 576.
 - II. Claims 1, 2, 4-7, 10, 12, 17, 18, 40-42, 44-46 drawn to a method of treating cancer by administering to the patient a compound of formula I, wherein the Y2 is a bond, L is unsaturated carbon chain, other than those defined in group I, X1, X2 together with the carbon attached is a hydroximic acid group, Y2 is CH2, classified in class 514, subclass 576.
 - III. Claims 1, 2, 4-7, 10, 12, 17, 18, 40-42, 44-46 drawn to a method of treating cancer by administering to the patient a compound of formula I, wherein the L is

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saturated carbon chain, X1, X2 together with the carbon attached is a hydroximic acid group, Y2 is CH₂, classified in class 514, subclass 576.

- IV Claims 1, 2, 4-7, 10, 12, 17, 18, 40-42, 44-46 drawn to a method of treating cancer by administering to the patient a compound of formula I, wherein X1, X2 together with the carbon attached is a hydroximic acid group, and the compound is other than those defined in groups I-III, classified in class 514, subclass 576.
- V Claims 1, 2, 4-7, 10, 12, 17, 18, 40-42, 44-46 drawn to a method of treating cancer by administering to the patient a compound of formula I, wherein X1, X2 together with the carbon attached is a carboxylic acid or ester, , classified in class 514, subclass 557.
- VI Claims 1, 3-7, 9-19, 21, 23-28, 30, 32-34, 36, 38, 42, 44-46 drawn to a method of treating cancer by administering to the patient a compound of formula I, wherein X1 is sulfur, classified in class 514, subclass 513.
- VII Claims 1-7, 9-18, 21-24, 32-42, 45-46 drawn to a method of treating cystic fibrosis by administering to the patient a compound of formula I, classified in class 514, subclass 513, 556, 576.
- VIII Claims 1-7, 9-18, 21-24, 32-42, 45-46 drawn to a method of wound healing by administering to the patient a compound of formula I, classified in class 514, subclass 513, 556, 576.
- IX Claims 1-7, 9-18, 21-24, 32-42, 45-46 drawn to a method of treating hair growth by administering to the patient a compound of formula I, classified in class 514, subclass 513, 556, 576.

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X Claims 1-7, 9-18, 21-24, 32-42, 45-46 drawn to a method of treating disorders other than those defined above by administering to the patient a compound of formula I, classified in class 514, subclass 513, 556, 576.

XI Claims 43, 47-53 drawn to a method of inhibiting histone deacytylation in cells, not associated with treating a disorder by using a compound of formula I, classified in class 514, subclass 513, 556, 576.

2. Inventions groups (I-X) and group XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions.

3. Inventions groups (I-VI), VII, VIII, IX and group X are unrelated from each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Particularly, the methods are directed to treatment of etiology distinct disorders.

4. Inventions groups I-VI are unrelated from each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operations. Particularly, the compounds employed in each of the groups are distinct from each other as to the structural features.

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5. Each of the above groups are further restricted into following groups based on the distinct structural features of moiety A in formula I:

a) wherein A is phenyl groups,

b) wherein A is naphthyl, indanyl or tetrahydronaphthyl groups,

c) wherein A is C3-14 cycloalkyl, or C4-C14 cycloalkenyl group, other than those defined in groups a, and b,

d) wherein A is saturated or unsaturated branched C3-12 hydrocarbon chain,

6. e) wherein A is heterocyclic moiety.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

It is well settled patent law that a Markush group must contain an immutable structural core responsible for the claimed activity. Applicant fails to provide an immutable central core structure for the proffered claims thereby presenting an improper Markush group for examination. Failure to link the claimed compounds with an immutable core structure results in claims reading on more than one invention, requiring restriction under 35 USC 121.

The above delineated inventions are independent and patentably distinct each from the other. The grouped inventions differ chemically, a reference which would anticipate the invention of one group would neither anticipate, nor make obvious the inventions in the other

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groups. As applicants argued in the response filed November 3, 2004, an unsaturated carbon chain would not be obvious over saturated carbon chain; the distinctness among the groups is much more than the difference of a double bond. The searches are not co-inclusive as indicated by the diverse chemical nature of the subject matter. One skilled in the art would readily practice the invention of one of the above groups without infringing and/or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

8. Claims 1-7, 9-18, 21-2432-47 are generic to a plurality of disclosed patentably distinct species comprising a variety of compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
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